UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: *United States of America, ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, CIVIL ACTION NO. 06–CV-11337-PBS *United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS; and *United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp., et al.*, Civil Action No. 07-10248-PBS	Hon. Patti B. Saris

STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF UNITED STATES' MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN OPPOSITION TO ABBOTT LABORATORIES INC.'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Local Rule 56.1, the United States hereby submits its Statement of Undisputed Material Facts Applicable to the Abbott Laboratories, Inc., in Support of its Motion for Partial Summary Judgment. Additional Undisputed Material Facts, which are common to Abbott Laboratories, Inc., the Dey Defendants, and the Roxane Defendants, are set forth in a separate United States' Local Rule 56.1 Statement of Undisputed Material Facts Applicable to

All Defendants, filed herewith.[1]

ABBOTT CORPORATION, ITS PRODUCTS AND LEADERSHIP

1. Abbott Corporation at all times material from 1991 until 2003 operated a division it called the Hospital Products Division ("Abbott HPD"). (Amended Complaint ¶ 30)(Answer ¶ 30)

2. HPD sold all of the drug products that are at issue in this lawsuit. These categories of products, which are sold under 44 different NDCS depending upon packaging size and volume, are Vancomycin; Dextrose; Saline; and Sterile Water ("Subject Drugs"). These products are used for hydration, irrigation and as diluents. (Amended Complaint ¶ 30)(Answer ¶ 30)

3. All of the Subject Drugs were "multi-source" drug products, which could be acquired from any number of competing pharmaceutical manufacturers, including Abbott HPD. (Amended Complaint ¶ 52)(Answer ¶ 52)

4. All of the Subject Drugs were generic products that are eligible for reimbursement under Medicare and Medicaid. Sellers 30b6, 3/31/08 at 378:10-15 (Lavine Decl. Exh. 88 & 89)

5. Vancomycin, a potent antibiotic was an important product for Abbott HPD that was launched in 1989. Sellers 30b6, 3/16/08 at 54:10-15; Sellers 30b6, 3/31/08 at 592 & Sellers 30b6 Exh. 27. (Amended Complaint ¶ 53)(Answer ¶ 53) (Lavine Decl. Exh. 70, 88, 125)

6. In 1996, HCFA stopped reimbursing vancomycin as a Durable Medical

[1] The United States reserves the right to argue that, to the extent any particular statement of fact is genuinely disputed, it is immaterial.

Equipment pharmacy benefit under Medicare as accelerated use of Vancomycin caused concern that its overutilization could impact Vancomycin's effectiveness as an antibiotic of last resort. Sellers 30b6, 3/31/08 at 590:18-22; 591; 592:1-3; 611:11-22; 612:1 & Sellers 30b6 Exh. 27. (Lavine Decl. Exhs. 89, 70)

7. Vancomycin's overall gross utilization was higher in the Alternate Site ("Alt Site") markets in or around 1996 than it was in hospitals, and by 1996 Abbott had acquired 60 percent share of the Vancomycin Alternate Site market. Sellers 30b6, 3/31/08 at 590:18-22; 591; 592:1-16; Sellers 30b6 Exh. 27. (Lavine Decl. Exhs. 70, 89)

8. Dextrose, Saline and Sterile Water, generic products which Abbott "launched" as new products offered by Abbott decades ago, are low cost (on average approximately $0.20 to $2.00), ubiquitous in the marketplace, and used in high volumes daily in the Alt Site market. Robertson Dep. 78:18-25; 79:1-25; 80:1-19; Kipperman Dep. 92:8-25; 93:1-5; Ormond Decl. Appendix A, Attachment 1-45 (Lavine Decl. Exhs. 1, 100, 101)

9. HPD was divided into two separate components: the Hospital Business Section ("HPD HBS"), which sold exclusively to the hospital market HPD Alt Site. Mershimer Dep. 43:7-13; Sellers 3/16/08 30b6 at 97-98 (Lavine Decl. Exh. 88, 98)

10. Abbott's HPD Alt Site itself was further subdivided into three units, Alternate Site Product Sales ("HPD Alt Site"), which sold to the non-hospital market through contracts and group purchasing organization arrangements, and Alternate Site Home Infusion ("Home Infusion"), which sold products under consignment arrangements and also facilitated reimbursement and other operational aspects of Abbott's wholly owned home infusion pharmacies. The third unit was a Renal business unit. Mershimer Dep. 43:7-13 (Lavine Decl.

Exh. 98)

11. In or after 1991, Abbott operated its own home infusion pharmacies in New Jersey and Los Angeles, and Chicago, which closed in 1996, 1998, and 2001 respectively. Sellers 30b6, 3/31/08 at 485:4-22. (Lavine Decl. Exh. 88)

12. During the claims period, Abbott maintained a provider number and had a provider agreement with HCFA, which enabled Abbott to bill Medicare and Medicaid directly on its own behalf. See Kreklow 02/08 Dep. at 121. Abbott Answer at ¶ 117 (Dkt. 5232) (Lavine Decl. Exh. 116)

13. Richard Gonzalez, served as the Senior Vice President and then President of HPD from 1998 to 2000, and then vice president for Medical Products and the president of Abbott's Medical Products, in 2000 and 2001. Abbott's Health Systems had oversight over HPD in 2000 to at least 2003. Gonzalez Dep. 25: 15-22; 26-28; 29:1-18; 44:4-11; 102:1-17; 113:2-19; 207:4-22; 208:1-14 & Exhs. 1 & 4. (Lavine Decl. Exh. # 82, 87, 102)

ABBOTT'S REPORTED PRICES WERE FALSE

14. The United States' expert, Mark G. Duggan, has analyzed the transaction data produced by Abbott in this case. The transaction data is a copy of the data used by Abbott in the ordinary course of business. Among other things, Dr. Duggan has used Abbott's transaction data to analyze the prices at which Abbott products were being sold directly by Abbott to customers and the prices at which the Abbott products were being re-sold by wholesalers and distributors to end customers. The Abbott transaction data included rebates paid to customers for 1996 to 2001, but no rebate information was included for any dates prior thereto. The rebates reflected in the Abbott data ranged from 5% to 7.5% and on average were approximately 6.3%. Dr. Duggan did

not include the rebates in his calculations of the prices at which Abbott's products were sold. Dr. Duggan did not include prompt pay discounts in his calculations of the prices at which Abbott's products were sold. Abbott, DT p. 19, 36, 37, Table 7; Henderson Exh. 41, Declaration of Mark Duggan ("Duggan Decl. ___"), ¶¶ 25, 31, 34, Attachment A.

15. As part of his analysis, Dr. Duggan used Abbott's transaction data to calculate the average and 95th percentile prices at which the Abbott products were sold directly by Abbott to all customers, to those customers identified by Abbott in its data as being in the retail pharmacy class of trade, and to those customers identified by Abbott in its data as wholesalers and distributors (net of chargebacks). Dr. Duggan also used Abbott's transaction data to calculate the average and 95th percentile prices at which the Abbott products were re-sold by wholesalers and distributors to all customers and to end customers identified by Abbott in its data as being in the retail pharmacy class of trade. Duggan Decl. ¶¶ 31, 34, Attachment A, Abbott 56.1 Exh. DT, Table 5, 10, 13b.

16. On average there was a difference of approximately 2% between the prices at which Abbott sold its products to wholesalers and distributors as compared to the prices at which the wholesalers and distributors re-sold the Abbott products to end customers. Abbott 56.1, Exh. DU, pp. 18-19, Table 6.

17. The customers identified by Abbott in its data as being in the retail pharmacy class of trade paid approximately 20% higher on average than the price paid by all of Abbott's customers both in the direct sales by Abbott and in the indirect sales by the wholesalers and distributors. Duggan Decl. ¶ 31.

18. In his damage calculations, for each NDC in each quarter, Dr. Duggan replaced

the AWP in each state pharmacy reimbursement logarithm with a price equal to 125 percent of the average pharmacy *indirect* price, he replaced the WAC by the average pharmacy-specific price in Abbott's *indirect* transaction data, and he replaced the Direct Price with Abbott's average, pharmacy-specific price in the *direct* transaction data. Abbott 56.1, Exh. DU, p. 9.

19. Appendix A to the Declaration of Patrick Ormond lists the List Prices, AWPs and average transaction prices for the 44 NDCs at issue in this case. Mr. Ormond is a Certified Public Accountant and is currently employed as an Auditor in the United States Attorney's Office, District of Massachusetts. His responsibilities include the investigation into the financial aspects of legal matters. (Lavine Decl. Exh. 1, (Declaration of Patrick Ormond (Ormond Decl.), Appendix A)).

20. To prepare the appendices and attachments to his declaration, Mr. Ormond reviewed the list prices Abbott reported to the publishers of the Red Book and the Blue Book (also known as the National Drug Database File or the "NDDF database"), the prices published by Red Book and the NDDF database as the Average Wholesale prices ("AWPs"), and the average selling prices ("Average Prices") calculated by Dr. Mark Duggan using Abbott's transaction data. Ormond Decl., ¶¶ 3, 6.

21. Attachments A1 through A44 contained in Appendix A of the Ormond Decl. graphically summarize four prices for each of the Subject Drugs over the time period of 1991 through 2002. The prices are: the Abbott reported list prices, the RedBook published AWPs, the NDDF published AWPs, and the Average Prices as calculated by Dr. Duggan. The data points in these attachments were based upon and accurately summarize the data contained in Appendix B of the Ormond Decl., Schedules B1 through B4 which allow for a comparison between the data

sets. Ormond Decl., ¶ 4.

22. Attachment A45 contained in Appendix A of the Ormond Decl. calculates, for each quarter for each of the Abbott NDCs, the numerical percentage "spread" between the NDDF published AWPs and the Transaction Based Average Prices as calculated by Dr. Duggan. These spreads are the numeric calculations of the spreads reflected graphically on Attachments 1 through 44. Mr. Ormond calculated the spreads by the following formula:

(NDDF published AWP - Average Prices) / Average Prices

The numerical percentage spreads in Attachment A45 accurately summarize the data contained in Appendix B of the Ormond Decl., Schedules 1 through 4. Ormond Decl., ¶ 5.

23. Mr. Ormond obtained most of the Abbott list prices from copies of Abbott catalogs provided to us by Abbott during discovery, namely, catalogs for the years; 1990, 1991, 1992, 1993, 1994, 1995, 1996, 1997 (partial), 1998, 2001 and 2002. The 1997 catalog Abbott provided was missing the pages which contain all NDCs prior to NDC 2422-12. One of the NDCs listed in this matter, 1966-07, was among those missing. For Abbott list prices for the year 1999, Mr. Ormond used the prices as attached in an email from Abbott employee Jerrie Cicerale to a Kathy (last name unknown) at First DataBank. The email is dated April 15th, 1999, is Bates Stamped ABT-DOJ0191058 and was produced by Abbott in discovery. There was no price catalog produced for the year 2000. Mr. Ormond also reviewed two email transmissions of wholesale price data which were sent to FDB by Abbott with effective dates of May7, 2001 and May 7, 2002 which are Bates Stamped CA- ABT006514 and ABT-DOJ-E 0219570 and were produced by Abbott in discovery. The Abbott list prices which Mr. Ormond identified in the forgoing documents are truly and accurately summarized in Schedule B1 of Appendix B to the

Ormond Decl. ¶ 7.

24. Mr. Ormond obtained the published Red Book prices published annually by Thomson Publishing (and in the early years, Medical Economics) by looking the prices up in copies of the actual Red Books. Mr. Ormond used Red Books published in 1991 through 2004. He prepared a summary of the prices listed in the Red Books as being the AWPs for the Abbott Drugs. The Red Book AWPs which Mr. Ormond identified in the published Red Books are truly and accurately summarized in Schedule B2 of Appendix B of the Ormond Decl. Ormond Decl., ¶ 8.

25. Mr. Ormond obtained the published BlueBook (FDB) prices from the First Databank NDDF database, which he was provided by Ian Dew of Steck Consulting. A true and accurate copy of the NDDF prices provided to Mr. Ormond by Mr. Dew is printed out in Schedule B3 of Appendix B of the Ormond Decl. Ormond Decl. ¶ 9.

26. Mr. Ormond obtained from Mr. Dew a copy of the Average Prices calculated by Dr. Duggan using Abbott's transaction data. Ormond Decl., ¶ 10.

27. Mr. Ormond calculated the percentage differences between the Abbott list prices found in the Abbott catalogs and the AWPs published in the Red Books and in the FDB NDDF database. From 1991 to 2000, Mr. Ormond found that the vast majority of the published AWPs were approximately 18.75% higher than the Abbott list prices contained in the Abbott catalogs and e-mails. Schedules B5 and B6 of Appendix B of the Ormond Decl. lists these comparisons. Ormond Decl. ¶ 11.

28. For the years 2001 and 2002, Mr. Ormond compared the published FDB NDDF database prices to the Abbott wholesale prices as reported to NDDF in emails dated April 30,

2001 and May 7, 2002. During this time period, Mr. Ormond found that the majority of the FDB NDDF database AWPs were approximately 25% higher than the wholesale prices provided by Abbott. Schedule B7 of Appendix B lists these comparisons. Ormond Decl.¶ 12.

ABBOTT'S UNDERSTANDING AND USE OF CERTAIN PRICING TERMS

29. From 1991 until at least 2001, Abbott HPD defined "List Price" as "the highest price published for a product in the catalog and/or submitted to the industry clearinghouses (Redbook and First Databank) for general distribution." Sellers 30b6, 3/16/08 at 261:1-14 & Sellers 30b6 Exh. 15. (Lavine Decl. Exh. 88 & 69)

30. Abbott understood that the provision of AWP information to customers could constitute a component of what was needed to establish a spread, and that it was an essential component to spread marketing. Fishman 30(b)(6), 3/20/08 at 673:18-22; 674; 675:1-6. (Lavine Decl. Exh. 91)

31. Abbott employees knew that there was or may have been a relationship between AWP and Medicare and Medicaid reimbursement. Dep. 24:25: 25:1-2; 72:10-15; 73:24-25; 74:1-5; 124:12-17; Heggie 5/17/07 Dep. 40:11-13; 48: 1-16; 156:7-19; 158:13-17; 162:1-11; 165:4-22; 166:1-22; 168:6-22; 169:1; 219:3-8; Brincks Dep. 44:19-25: 45:1-4; 53:9-25; 54:1-3; 62: 21-25; 63:1-24; 144:24-25; 145: 1-23; 164:1-25; 216:14-25; 262:18-25: 263:1. (Lavine Decl. Exh. 103; 104)

32. National Accounts manager Christine Snead testified that it was common knowledge among the Abbott sales representatives and anyone in the marketplace that Abbott's customers used AWP for reimbursement. Ms. Snead further understood that AWP was involved in reimbursement. She could not think of any other reason why a customer would want AWP

information other than to do an analysis on reimbursement spread. Snead Dep. 24:25: 25:1-2; 72:10-15; 73:24-25; 74:1-5; 124:12-17 (Lavine Decl. Exh. 105)

33. An Alternate Site reimbursement manager, Michael Heggie, testified that "AWP is a function of list." Mr. Heggie further testified that he would agree that the AWP for a drug is relevant to the pharmacies, to insurance companies, to Medicare and Medicaid. He further testified that Abbott knew Redbook information, including AWPs, was transmitted to Medicaid and Medicare programs and that he understood that the price reporting compendium Redbook added an 18.75 percent markup to the list to publish AWP. Testifying further, Mr. Heggie acknowledged that he knew that there was a discrepancy between list price and sales price, that list price was higher, and that the compendia used the list price to come up with the published AWP. Heggie 5/17/07 Dep. 40:11-13; 48: 1-16; 156:7-19; 158:13-17; 162:1-11; 165:4-22; 166:1-22; 168:6-22; 169:1; 219:3-8. (Lavine Decl. Exh. 103)

34. Mr. Heggie testified that AWP-based reimbursement was "senseless" based in part on certain prices being reported by manufacturers. Mr. Heggie thought it was "senseless" to use a list price that was significantly higher than sales price for these drugs because "everyone knew that it was not the most economical way to pay for drugs or to pay for whatever they were marking up" . Heggie 5/17/07 Dep. 40:11-13; 48: 1-16; 156:7-19; 158:13-17; 162:1-11; 165:4-22; 166:1-22; 168:6-22; 169:1; 219:3-8 . (Lavine Decl. Exh. 103)

35. David Brincks, who was the manager of Alt Site Home Infusion contracting marketing, testified that Abbott Home Infusion used AWP and that he understood that a basic relationship existed where personnel from Abbott hospital products reported information to the pricing services such as First Data Bank and Red Book. Brincks Dep. 62: 21-25; 63:1-24.

(Lavine Decl. Exh. 104)

36. Mr. Brincks agreed that at least in the context of the Vancomycin price change. In 1995 which he was involved with, he had an understanding that there was a formulaic relationship between the list prices set by Abbott and the AWPs that were published for those Abbott products. The formula involved multiplying list times 1.1875 to arrive at AWP. Brincks Dep. 216:14-25; 262:18-25: 263:1. (Lavine Decl. Exh. 104)

37. Home Infusion was never involved in the process of list price setting. Brincks Dep. 164:1-25. (Lavine Decl. Exh. 104)

38. Mr. Brincks knew home infusion customers cared about AWP because AWP "was the standard process that was used to actually bill in the industry. AWP was a common reference point accepted and used in – broadly in the home infusion market to bill patients and insurance companies". Brincks Dep. 53:9-25; 54:1-3. (Lavine Decl. Exh. 104)

SETTING OF ABBOTT'S LIST AND CONTRACT PRICES

39. For Abbott HPD, the setting of catalog and list prices was usually an annual process for the period from 1991 until 2001. The setting of catalog prices was a process led by the HBS Contract Marketing managers. Sellers 30b6, 3/16/08 at 35:22; 36:1-10; 39:8-16; Abbott response to U.S. Second RFAs 32 & 33. (Lavine Decl. Exh. 88)

40. Abbott asserts that in setting its pricing, Abbott HPD only considered the product investment and customer needs and that the following were never considered or factored in any way into setting its List Price setting the following: a) Medicare or Medicaid reimbursement; b) waste, breakage, drug procurement costs, or bad debts; c) inventory carrying costs; d) dispensing fees or administration fees; e) co-pay risks to the provider; or, f) complaints from providers about

needing AWPs to recover dispensing fees. Abbott HPD price setting employees never considered whether any complaint about provider dispensing fees or administration fees justified reporting inflated List Prices. Sellers 30b6, 3/16/08 at 375:8-20; 362:22; 347:19-22; 348:1-17; 350:13-17; 363:1-6; Sellers 30b6, 3/31/08 at 350:9-12; 607:13-17; 608:1-11. (Lavine Decl. Exh. 88 & 127)

41. Abbott never considered medical concerns about the overutilization of Vancomycin in its decision making concerning the setting of its Vancomycin list prices. Sellers 30b6, 3/31/08 at 612:3-8; Sellers 11/1/07 Dep. 229:17-22; 230:1. (Lavine Decl. Exh. 89 & 126)

THE CAUSE OF THE SPREAD

42. From 1991 until 1999, Abbott took an inflationary price increase each year at a rate of three to five percent on its list prices while at the same time its contract prices decreased on its HPD drugs as a result of market competitive forces. Sellers 30b6, 3/16/08 at 58:21-22; 59:1-22; 60:1-3; 97:9-19; 104:1-12; 354:6-22; 355:1-6. (Lavine Decl. Exh. 88)

43. Abbott HPD admits that it could have at any time from 1995 until 2001 dropped its list prices on Vancomycin. Sellers 30b6, 3/31/08 at 577:7-22; 578:1-21. (Lavine Decl. Exh. 89)

44. Despite the fact that HBS took annual list prices increases, over the period from 1991 to 2000, the HPD contract prices decreased, which, in turn, increased the disparities between list and contract prices on HPD products. Sellers 30b6, 3/16/08 at 103:8-21. (Lavine Decl. Exh. 88)

45. The increase of list prices annually was controlled by the HBS product management, who had sole responsibility for taking the annual inflationary increases in list price

that caused the disparities from 1991 until 2000. Sellers 30b6, 3/16/08 at 98:20-22; 99:1-12. Sellers 30b6, 3/16/08 at 213:4-22; 214:1-33; 215:1-19 (Lavine Decl. Exh. 88)

46. Even though the HPD HBS set list prices on all the HPD products sold by Alt Site, Abbott claims that its HPD HBS managers were not aware of information regarding HPD Alt. Site payors, including Medicare and Medicaid. Sellers 30b6, 3/16/08 at 96:2-22, 97:1-7. (Lavine Decl. Exh. 88)

47. The pricing guidelines implemented by Abbott HPD in 2001, which required list price to be set at 5% above its real average wholesale price is the same policy Abbott's Pharmaceutical Products division had maintained since before 1991. Sellers 30b6 Exh. 33 & 34 (Lavine Decl. Exh. 73 & 74)

48. By 2001, a large disparity between contract price and list price existed for a number of HPD products, including the Subject Drugs. Sellers 30b6, 3/16/08 at 98:11-15; Ormond Decl., Appendix A. (Lavine Decl. Exh. 88)

49. There was no HPD HBS business reason for the existence of large disparities or "spreads" on the HPD products, including the Subject Drugs. Sellers 30b6, 3/16/08 at 98:16-19. (Lavine Decl. Exh. 88)

50. The HPD HBS management that controlled prices did not monitor the "differential," or spread, between list price and contract price from 1991 to 1999. Sellers 30b6, 3/16/08 at 213:4-22; 214:1-33; 215:1-19. (Lavine Decl. Exh. 88)

51. Abbott testified that HPD HBS managers from 1991 until 1999 were not trying to reconcile the difference, or "spread" between list price and contract price. Sellers 30b6, 3/16/08 at 98: 16-22; 99:5-22; 100:1-6; 215:21-22; 216:2-18. (Lavine Decl. Exh. 88)

52. The HPD HBS had sole responsibility for taking the annual inflationary increases in list price from 1991 until 2000 that contributed to the growing disparities between contract and list prices on HPD products. Sellers 30b6, 3/16/08 at 98:20-22; 99:1-12. (Lavine Decl. Exh. # 88)

53. Abbott testified that HPD HBS maintained HPD list prices to have a price to use to sell to non-contract customers. Abbott further testified that its managers setting these prices from 1991 until 1999 did not focus on the large disparities or attempt to reconcile them. Sellers 30b6, 3/16/08 at 98:16-22; 99:5-22; 100:1-6; 215:21-22; 216:2-18. (Lavine Decl. Exh. 88)

54. After undertaking an evaluation in 2001, Abbott HPD determined that other than to capture elevated prices on non-contract sales, there was no business purpose for having a list price that was one hundred, two hundred, three hundred, or up to a thousand percent higher than what the contract price was, and, in 2001, Abbott HPD decided it should bring its list prices more in line with its contract prices. Sellers 30b6, 3/16/08 at 98:11-19; 216:1-19; 215:21-22. (Lavine Decl. Exh. 88)

55. As early as June 1991, the HPD Alt Site Vice President Donald Robertson conceded sending a memo to the then HPD President Kris Kringel, among others, that if the government abandons AWP as a good indicator of product acquisition cost, it would have significant implications for HPD's Alt Site business. Mr. Robertson sent the memo to the HPD President to keep him informed. Abbott response to U.S. Second RFAs 49; Robertson 9/13/07 Dep at 37:11-25; 38:1-4;169:15-25; 170:1-11; 171:1-25; 172: 1-25;174:23-25; 175:1-4 & Robertson Exh. 2. (Lavine Decl. Exh. 83, 100 & 127)

DECISION TO CHANGE REPORTED LIST PRICING IN '01

56. After receiving word of the 2000 HHS-OIG subpoena, Richard Gonzalez, HPD President, requested in-house counsel review and investigate the disparities between list prices and contract prices hoping it would "reduce the controversy." As a result, beginning in 2000, Abbott evaluated its list pricing for HPD products, including the Subject Drugs. Sellers 30b6, 3/16/08 at 48:22; 49:1; 52:2-22; 53:1-22; 54:1-7; 57:1-4; 68:1-5. 72:5-22; 73: 1-23; Sellers 30b6 Exh. 35-36; Gonzalez Dep. 123:15-22; 124: 125:1-14; 134:3-11. (Lavine Decl. Exh. 75, 76, 88 102, & 102)

57. In April 2001, Abbott lowered its list prices that it both reported in its price catalog and that it reported to the pricing compendia. The List Price changes included drastic reduction of up to 70 to 90 percent in the catalog and compendia reported list prices for the Subject Drugs. (Sellers 30b6, 3/16/08 at 66:1-10 & Sellers 30b6 Exh. 34-36; Sellers 30b6, 3/31/08 at 662:6-22; 663:1-17 & Sellers 30b6 Exh. 35) (Lavine Decl. Exh. 74, 75, 76, 88 & 89)

58. Abbott HPD's public explanation for its 2001 List price changes was that it wanted to bring its list prices more in line with prevailing market prices. Mr. Gonzalez made the final decision to change the prices due to Congressional inquiries and press concerns. Sellers 30b6, 3/16/08 at 81:13-16 & Sellers 30b6 Exhs. 34-36; Gonzalez Dep. 123:15-22; 124: 125:1-14; 327:3-22; 328:1-6. (Lavine Decl. Exhs. 74, 76, 88, 102)

59. Abbott claims that it did not lower its list prices to more properly align its list prices with its prevailing contract prices prior 2001 because Abbott had not determined that these disparities were an issue until the fall of 2000. Sellers 30b6, 3/16/08 at 68:1-5. (Lavine Decl. Exh. 88)

60. Abbott's in-house counsel assigned responsibility for the 2000 pricing review to Michael Sellers. The review took 5 months to complete and determined that for certain Abbott products there were large differences between List and Contract prices. Sellers 30b6, 3/16/08 at 50:5-21; 52:1-22; 53:1-22; 54:1-7 (Lavine Decl. Exh. 88)

61. The analysis also demonstrated that less than one percent of Abbott's sales were actually at list price in 2001. Prior to 2001, Abbott had never analyzed what percentage of the sales on the Subject Drugs were made at list price. Sellers 30b6, 3/16/08 at 54:17-20; 55:3-7; 57:1-22; 58:1-19; 106:22; 107:1-22; Sellers 30b6, 3/31/08 at 585:13-17, and Sellers 30b6 Exh. 33 & 34. (Lavine Decl. Exhs. 73, 74, 88, 89)

62. According to Abbott's sales data, with a single exception, less than two tenths of one percent of Abbott's sales were at list price each year from 1991 until 2001. (Dew Decl. ¶¶ 7, 8, 9) (Lavine Decl. Exh. # 2)

63. In 2001, Abbott lowered its HPD generic list prices, including the prices on the Subject Drugs, because it wanted to more properly align its list prices with its prevailing contract prices. Sellers 30b6, 3/16/08 at 67:6-21. (Lavine Decl. Exh. # 88)

64. In 2001, the decision to lower its HPD generic list prices, including the prices on the Subject Drugs, because Abbott believed it was the right time and the right thing to do. Sellers 30b6, 3/16/08 at 67:6-21. (Lavine Decl. Exh. # 88)

65. By 2000, Abbott knew that there was a significant level of discourse within the U.S. Congress, as well as press write-ups, concerning the issue of disparities between list prices and contract prices on pharmaceuticals. Sellers 30b6, 3/16/08 at 69:1-22;70:1-22; 71:1-10 (Lavine Decl. Exh. 88)

66. In 2000, Abbott received a letter from Congressman Fortney "Pete" Stark concerning Abbott's AWP spreads and price reporting. Congressman Stark urged Abbott to stop reporting inflated prices and asked that Abbott's CEO share the letter with Abbott's Board of Directors and Corporate Integrity Committee. Abbott never responded to the Stark Letter. U.S. Second Set of Requests for Admission (Second RFAs) to Abbott 6 & 7; Abbott response to U.S. Second RFAs 6 & 7; Letter from Congressman Stark (Lavine Decl. Exh. 66, 127, 128)

67. Other than concern about Congressional scrutiny and press coverage, coupled with Abbott's desire to align its list prices with its actual contract prices, no other factor caused or contributed to Abbott's decision to lower its prices in 2001. Sellers 30b6, 3/16/08 at 67:6-21; 68-71; 72:5-11. (Lavine Decl. Exh. 88)

68. In 2001, Abbott HPD adopted new "pricing guidelines" which established a policy under which list prices were set at 5% above its actual WAC. Sellers 30b6, 3/16/08 at 243:14-22 & Sellers 30b6 Exhs. 15, 33-36. (Lavine Decl. Exhs. 69, 73, 74, 75, 76, 88)

69. After the price change in 2001 and adoption of Abbott's revised pricing policy, Abbott HPD's defined WAC in 2001 to mean "the price of a product when sold to a drug wholesaler who is eligible for chargeback processing after the end sale to a contract provider." Sellers 30b6, 3/16/08 at 262:15-22; 263; 264:1-16 & Sellers 30b6 Exh. 15 (Lavine Decl. Exhs. 69, 88)

70. The pricing guidelines implemented by Abbott HPD in 2001, which required list price to be set at 5% above its real average wholesale price is the same policy Abbott's separate Pharmaceutical Products division had maintained since before 1991. Sellers 30b6 Exh. 33 & 34. (Lavine Decl. Exh. 73)

1995 VANCOMYCIN PRICE CHANGE

71. Abbott changed it prices for Vancomycin for a brief period in 1995. Sellers 30b6, 3/31/08 at 425:5-22; 426:1 & Sellers 30b6 Exh. 27, 28 & 29. (Lavine Decl. Exh. 70, 71, 72, 88)

72. Abbott's List Price for its 1-gram Flip Top Vial Vancomycin, NDC 00074-6533-01, in its 1994 Price Catalog was $50.90. (Lavine Decl. Exh. 7, p. 22)

73. The average indirect price to pharmacies for Abbott's 1-gram Flip Top Vial Vancomycin, NDC 00074-6533-01 in 1995Q2 was $6.57407. Declaration of Pat Ormond, Schedule B4, page 15.

74. The AWP published in the 1995 Red Book for a 1-gram Flip Top Vial Vancomycin, NDC 00074-6533-01 was $604.44 for a package of 10 which is the equivalent of $60.44 for a single 1-gram Flip Top Vial. The AWP published in the NDDF for a 1-gram Flip Top Vial Vancomycin, NDC 00074-6533-01 (with an effective date of 4/4/94) was $60.44. Declaration of Pat Ormond, Schedule B3, page 4. (Lavine Decl. Exh. 34, page 27)

75. On March 20, 1995, Abbott employees internally agreed to change the "list (catalog)" price on three sizes of Abbott's vancomycin products, including its 1-gram Flip Top Vial Vancomycin, NDC 00074-6533-01. The internal e-mail used to communicate the agreement indicated that Redbook and Medi-Span should be notified of the price changes "ASAP" and that Redbook and Medi-Span "are the sources for creating the AWP that is important to Alternate Site." Sellers 30b6 Exh. 25 (Lavine Decl. Exh. 129)

76. Abbott employees prepared a spreadsheet which estimated the AWP that would result from a "suggested list price" of $15.00 by multiplying the list price by 1.1875 (identified as "awp as % of list"). Abbott employees thereby estimate that the AWP that would result from

their new list of $15.00 would be $17.81257. (Lavine Decl. Exh. 55)

77. On March 8, 1995, Abbott reported to Red Book, First DataBank and MediSpan that it List Price for its 1-gram Flip Top Vial Vancomycin, NDC 00074-6533-01, was $15.00, with an effective date of April 3, 1995. (Lavine Decl. Exh. 56)

78. On May 30, 1995, Abbott reported to Red Book, First DataBank and MediSpan that its List Price for its 1-gram Flip Top Vial Vancomycin, NDC 00074-6533-01, was $529.40 for a package of 10, equaling a price of $52.94 per 1-gram vial, with an effective date of April 3, 1995. (Lavine Decl. Exh. 58)

79. Abbott's List Price for its 1-gram Flip Top Vial Vancomycin, NDC 00074-6533-01, in its 1995 Price Catalog was $52.94. (Lavine Decl. Exh. 8, p. 22)

80. The AWP published in the 1996 Red Book for a 1-gram Flip Top Vial Vancomycin, NDC 00074-6533-01 was $628.66 for a package of 10 which is the equivalent of $62.87 for a single 1-gram Flip Top Vial. (Lavine Decl. Exh. 35, p. 29) The AWP published in the NDDF for a 1-gram Flip Top Vial Vancomycin, NDC 00074-6533-01 (with an effective date of 4/3/95) was $62.87. The average indirect price to pharmacies for Abbott's 1-gram Flip Top Vial Vancomycin, NDC 00074-6533-01 in 1996Q2 was $6.22023. Decl. of Pat Ormond, Schedule B4, pages 4 & 15. (Lavine Decl. Exh. 1)

81. A memorandum drafted by a reimbursement manager at HPD Alt Site warned "[h]aving a published list price which is high allows a provider to bill at that list price. Some customers who were buying our Vanco at a deep discount off list may ask about the price change." Sellers 30b6 Exh. 30 (4/26/95 Heggie Memo) (Lavine Decl. Exh. 130)

ABBOTT'S PRICE REPORTING TO THE COMPENDIA

82. When Abbott received civil investigative demands from the Department of Justice regarding its HPD list pricing on the Subject Drugs Abbott HPD did not ask for information or submit questions of the Government concerning the investigative demands. Sellers 30b6, 3/31/08 at 390:2-12 (Lavine Decl. Exh. 89)

83. Since 1991, Abbott has routinely reported list prices to three compendia: First Databank; Redbook; and Medispan. Sellers 30b6, 3/16/08 at 141:10-19; 142:1-16 (Lavine Decl. Exh. 1, 15-29, 88, 41-58)

84. Abbott provided its list prices to the compendia as opposed to some other price because it only reported its highest published prices. Sellers 30b6, 3/16/08 at 94:4-11; 261:22; 262:1-14. (Lavine Decl. Exh. 88)

85. Jerrie Cicerale was Abbott HPD's point of contact with the compendia from 1991 until 2001, and if she provided communications to any pricing compendia it can be authenticated as reflecting Abbott's list pricing, as reported in its catalogs. Sellers 30b6, 3/16/08 at 95: 4-9; 113:21-22; 114:1-6; 159:16-22; 160:1-16; 162:1-11; Cicerale 5/30/07 at 59:20-25; 60:1-4. (Lavine Decl. Exh. 88, 107)

86. Jerrie Cicerale viewed the catalogs informing about list price that HPD published as having no purpose and as constituting the equivalent of "junk mail." Cicerale 5/30/07 295:11-25; 296:1-5 (Lavine Decl. Exh. 107)

87. HPD employees knew that the price reporting compendia used Abbott's list prices to determine AWPs. Heggie 5/17/07 Dep. at 36:2-7 (Lavine Decl. Exh. 103)

88. The compendia determined Abbott's AWP by adding a mark-up of 18.75%.

Exhibit 24 to Redbook Deposition ("per Michael Heggie" mark up is 18.75% above direct/list); January 31, 2001 email from Kay Morgan to Jerrie Cicerale. (Sellers Exh. 586)(Lavine Decl. Exh. 131)

89. Abbott directed Redbook as to what mark-up over list price to use to set AWPs for Abbott's drugs. Kristen Minne (Red Book 30b6) Deposition at 209-10. Also Ex. 24 to Minne Dep (AWP mark-up 1.1875% per Abbott employee Michael Heggie). (Lavine Decl. Exh. 106 & 119)

90. Abbott employees were aware of the 18.75% markup. Heggie 5/17/07 Dep. At 38-39; Cicerale Deposition 176:20- 178:7. (Lavine Decl. Exhs. 88, 107)

91. On April 3, 2003, Redbook changed to a 20% mark-up on list after consulting with Abbott. Redbook 30b6 Deposition, Exhibit 24. (Lavine Decl. Exh. 119)

92. Abbott verified the prices reported for its products in the Redbook. *See* September 10, 1996 Price Listing Verification Transmittal from Jerrie Cicerale to Roni Lane at Redbook (Sellers 3); September 10, 2001 Price Listing Verification Transmittal from Jerrie Cicerale to Roni Lane at Redbook (Ex. 931 to Cicerale Dep.) (Lavine Decl. Exh. 52A-E; 108 A, B, C)

ABBOTT'S UNDERSTANDING OF USE OF COMPENDIA FOR PURPOSES OF MEDICARE AND MEDICAID REIMBURSEMENT

93. From 1991 until at least 2001, Abbott HPD understood that the compendia would publish its products and prices reported by HPD HBS. Sellers 30b6, 3/16/08 at 163:14-22; 164:1-2. (Lavine Decl. Exh. 88)

94. From 1991 until at least 2001, Abbott understood that the compendia would publish the information HPD reported concerning its products in the compendia databases and publications sold within the healthcare industry. Sellers 30b6, 3/16/08 at 163:14-22; 164:1-2.

(Lavine Decl. Exh. 88)

95. Abbott understood that a small group of employees within Home Infusion services reimbursement had information regarding how AWP or list price or WAC price factored into the Home Infusion reimbursement. Sellers 30b6, 3/16/08 at 174:6-22; 175:1-10 (Lavine Decl. Exh. 88)

ABBOTT'S PROVISION OF AWP OR SPREAD INFORMATION TO THIRD PARTIES OTHER THAN STATE OR FEDERAL OFFICIALS

96. It was Abbott HPD's practice that if a customer or GPO demanded AWP as part of the bid response, Abbott employees were authorized to provide that information. Sellers 30b6, 3/16/08 at 193:2-22; 194:1-12 (Lavine Decl. Exh. 88)

97. Abbott understood that customers may have told them that spread was of interest to Abbott's customers. Abbott also has seen documents where HPD Alt Site GPOS may have represented that AWP was an important factor in their decisions. Sellers 30b6, 3/16/08 at 207:21-22; 208; 209:1-9. (Lavine Decl. Exh. 88)

98. It was permissible under Abbott's practice to refer customers to Redbook or Medispan for AWP information. Sellers 30b6, 3/16/08 at 383:4-10. (Lavine Decl. Exh. 88)

99. Abbott provided bids in response to Gerimed's bid requests, and was awarded contracts, including ones for the subject drugs. Sellers 30b6, 3/16/08 at 231: 16-22; 232: 1-9 & Sellers 30b6 Exh. 12 (Lavine Decl. Exh. 88)

100. GPO Gerimed's bid requests to Abbott expressly stated that bids would be evaluated on a line by line basis, and that contract pricing would be evaluated based on lowest price and/or best spread for multi-source products. Sellers 30b6, 3/16/08 at 233:6-22; 234:1-7, & Sellers 30b6 Exh. 11 (p. ABT 277701-02) (Lavine Decl. Exh. 88, 132)

101. GPO Gerimed told Abbott HPD, and Abbott HPD understood, that AWP spread was a factor in Gerimed's bid award analysis. Sellers 30b6, 3/16/08 at 230:17-20; 233:6-22; 234:1-7, & Sellers 30b6 Exh. 11 (p. ABT 277701) and Sellers 30b6 Exh. 12 (all pages). (Lavine Decl. Exh. 88, 132)

102. Abbott HPD Alt Site was awarded GPO contracts due to its AWP spreads. The bid awards with spread information were provided to HPD Alt Site sales force, who could use the information to approach the GPO's members. Sellers 30b6, 3/16/08 at 231: 16-22; 232: 1-9 & Sellers 30b6 Exh. 12 (Lavine Decl. Exh. 88, 120)

103. On May 26, 1994, Abbott's Steve Kipperman sent a memorandum to the Abbott's Alt Site Field Sales Force and District Managers with attached AWP information. The memo stated: "As you are aware, on at [sic] the beginning of April, Abbott took a list price increase. This also has an effect on our AWP (Average Wholesale Price) which Redbook quotes for reimbursement purposes. Therefore, Mike Heggie was able to get Red Book to send a listing of the "new" AWP's for all of our products, which will be effective through next April. He stated: "I hope this information is helpful and if you have any questions, please feel free to contact me. (Kipperman Dep. Exh. 480) (Lavine Decl. Exh. 67)

104. Abbott HPD HBS maintained a resource manual for its HPD HBS employees called the Basic Operating Procedures Manual (BOP). The BOP at p. 247 included information for the HPD HBS employees concerning Redbook's formula of adding 18.75 percent to reported list prices to arrive at the AWP for the product. Weibking Dep. Exh. 35 (excerpt) at p. 247 (Lavine Decl. Exh. 133)

ABBOTT'S FAILURE TO SEEK GOVERNMENT APPROVAL

105. Abbott HPD did not at any time make any inquiry of any federal or state government official, state or federal, to seek clarification of the relationship between its price reporting or AWPs and Medicare or Medicaid reimbursement. Sellers 30b6, 3/16/08 at 179:6-10; 180:1-22 (Lavine Decl. Exh. 88)

106. Other than officials in Texas, Abbott HPD never advised state or federal Medicare or Medicaid officials about the pricing of the Subject Drugs or about list prices or its knowledge that its customers were awarding contracts to Abbott based on the AWP spread for Abbott drugs. Sellers 30b6, 3/31/08 at 487:2-22; 1-4; 491:14-22; 492:1-5. (Lavine Decl. Exh. 89)

107. Abbott HPD believes that its Home Infusion Reimbursement employees communicated with state medicaid payors and Medicare carriers so that it could understand how Abbott's HI clients were reimbursed by a particular state or carrier, and the relationships between WAC, AWP and Medicaid reimbursement. Sellers 30b6, 3/16/08 at 180:1-22; 181; 182:1-7 (Lavine Decl. Exh. 88)

108. The Home Infusion Reimbursement Department communicated with Medicare and Medicaid officials regarding the processing of claims. Sellers 30b6, 3/16/08 at 180:1-22; 181:1-4. (Lavine Decl. Exh. 88)

109. Abbott claims that it cannot identify when it first noticed the large disparities between contract prices and list prices for some of its HPD products, except to say that Abbott looked at a number of products in the fall of 2000. Sellers 30b6, 3/16/08 at 183:9-15. (Lavine Decl. Exh. 88)

110. Abbott never notified any state or federal official about the disparities or "spreads" between the contract and list price on its HPD drugs. Fishman 30(b)(6), 3/20/08 at 643:2-9;

Sellers 30b6, 3/16/08 at 183:17-22; 184:1-9. (Lavine Decl. Exh. 88, 91)

111. Abbott received a number of inquiries from the federal government concerning its list price setting and AWPS, to wit:

a. On January 22, 1996, the Attorney General issued a Civil Investigative Demand (CID) to Abbott seeking information pertaining to its HPD list price reporting and AWP spread maintenance practices for all of the Subject Drugs, except Sterile Water. In 1996 when Abbott received the CID from the Attorney General, it did not lower or consider lowering its list prices on the Subject Drugs, or other drugs referenced in the CID because when Abbott originally got the investigative demands, Abbott is not sure that anyone outside of its legal department understood what the issues were.

b. On October 31, 1997, HHS-OIG issued a subpoena to Abbott requesting documents and information pertaining to its HPD list price reporting and AWP spread maintenance practices in HPD products, including for the Subject Drugs.

c. On September 30, 1999, the Department of Justice issued a letter notifying Abbott of the Relator's *qui tam* suit and the allegations therein.

d. On August 28, 2000, HHS-OIG issued a second subpoena to Abbott requesting additional documents and information pertaining to its HPD list price reporting and AWP spread maintenance practices. Abbott refused to respond.

Klaus Exh. 3, 4, 6; Gonzalez Dep. Exh. 4; Sellers 30b6, 3/16/08 at 63:7-15; Sellers 30b6, 3/31/08 at 390:2-12. (Lavine Decl. Exh. 82, 88, 89, 121, 122, 123)

112. Abbott cannot explain why, when it received a CID in 1996, or the OIG subpoenas

in 1997 and 2000, or '99 DOJ letter, it did not further inquire of the federal government whether Abbott's price reporting was appropriate or consistent with Medicare and Medicaid policies. The government met with Abbott and discussed its liability theories in October and November 1999. Abbott also communicated with DOJ regarding the 2000 subpoena. Sellers 30b6, 3/16/08 at 188:5-22; 189; 190:1-18 August 28, 2000 Letter from Christopher Cook to Mark Lavine and Linda Hiller; November 3, 1999 Letter from Reed Stephens to Dan Reidy (referencing a October 27th meeting) (Lavine Decl. Exh. 64, 65, 88)

113. Abbott joined in the March and August memorandum and letters from other *qui tam* Defendants to the Department of Justice, arguing against intervention. March 17, 2000 Letter from Defendants to Assistant Attorney General David Ogden; August 25, 2000 follow-up letter Assistant Attorney General Ogden; September 1, 2000 letter from Dan Reidy to Reed Stephens joining the Defendants' Position Paper; October 5, 2000 follow-up letter from Defendants to Assistant Attorney General David Ogden. (Lavine Decl. Exh. 61, 65, 134, 135)

ABBOTT'S AVERAGE MANUFACTURER PRICE REPORTING (AMP)

114. Average Manufacturer Price or "AMP" as used by the HCFA and the Medicaid programs and is defined as, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, as defined under 42 U.S.C §1396r-8(k). As a participant in Medicare and Medicaid, Abbott provided what it purported to be AMP information from the implementation of OBRA 90 until after 2003. Abbott Response to First Set of Interrogatories by the United States Nos. 2, 16, 20 (Lavine Decl. Exh. 136)

115. Abbott HPD contends that its transactional prices could be inferred through Abbott's submission of AMP and 340b price reporting to the United States. Sellers 30b6, 3/16/08

at 315:8-22; 316:1-3. (Lavine Decl. Exh. 88)

116. In 1995, Abbott determined that it was incorrectly calculating its AMPs for HPD "from the beginning" because it misunderstood the definition of Average Manufacturer Price as it appeared in OBRA 90 Part 1 Reductions in Spending 4401(k)(1) and did not commit the resources necessary to properly administer the AMP calculation program. In some cases it was paying more in the rebate than it was being paid for the drug. Heggie Dep. 54:9-22; 55-56; 57:1-14; 59:13-17 & Heggie Exh. 789, 790, 792 (Lavine Decl. Exh. 77, 78, 79, 103)

117. Abbott personnel generated a document identifying examples of the Best Price and AMP differentials, wherein Abbott personnel commented that "These AMPs are totally distorted because in our calculation of AMP we did not figure in the charge backs, discounts to wholesaler class of trade, etc." Abbott met with HCFA representatives to seek credit for its rebate overpayments. Abbott Doc ABT-006256; Heggie Dep. 61:22; 62-71;72:1-14 & Heggie Exh. 795 & 796 (Lavine Decl. Exh. 80, 81, 103, 137)

118. During the second quarter of 1999, PriceWaterhouseCoopers[2] reviewed HPD's Medicaid and Public Health System Drug Pricing Programs (340B) to ensure compliance with the Medicaid drug rebate requirements of OBRA 90 and the Section 340B requirements under the Veterans Health Care Act of 1992, and determined that Abbott HPD should revise its Medicaid calculation process. Abbott then attempted in 2000 and 2001 to develop systems to "rapidly bring" the division into compliance with Medicaid and other federal quarterly reporting requirements. Patel Dep. 117:10-25;118:1-25 & Patel Exh. 991 at 4 of 20.. ABT-DOJ-E-1059745; ABT-DOJ-E-0445341; ABT-DOJ-E-0450594-5; ABT-DOJ-E-105936-68 at p. 4 of 33;

[2]Abbott has never produced the Price Waterhouse Coopers Medicaid and 340B program compliance audit to the United States or Relator.

ABT-DOJ-E 0423051-66 at p. 4 of 16; Patel Dep. 117:10-25;118:1-25 & Patel Exh. 991 at 4-20. (Lavine Decl. Exh. 84, 109, 138)

ABBOTT'S FAMILIARITY WITH MEDICARE AND MEDICAID AND REIMBURSEMENT

119. As early as 1996, Abbott established a group called the "Medicare Working Group", which was comprised of individuals from various parts of Abbott, including, HPD, PPD, Ross, and Abbott's government relations/lobbying group, among others, who met or conferred telephonically on a periodic monthly basis. Haas at 53:10-13; 56:4-6; 61:20-21; 62-65; 66:1-5 & Exh. 1121; J. Miller Dep at 52:8-22; 53:1; Tootell 73:3-16. (Lavine Decl. Exh. 110, 111, 112)

120. In December 1996, Medicare Working Group received a document that had been referenced in a Medicare Working Group meeting by Michael Tootell. The document was entitled "Medicare Part B Payment For Drugs Average Wholesale Price Issue" and put the group on notice of the following:

A. "Currently, Medicare pays for those drugs that are not reimbursed on a prospective basis or a cost basis at the lesser of the average wholesale price or the actual acquisition cost of the drug. . . Medicare pays at the average wholesale price level, because the program has not acquired acquisition cost information sufficient to establish reimbursement rates."

B. "There have been several studies and investigations into the appropriateness of using AWP as the determining factor for payment. The common conclusion of these efforts is that the use of AWP as a payment measure results in excessive reimbursement that is far out-of-line with the estimated acquisition costs of the drugs . . . ."

C. "[T]here is some evidence that often the AWP for a drug is set at a

particular level to establish third-party reimbursement, but has no relevance to any party beyond the third-party payer [sic]. For these reasons, the AWP issue is being presented and considered not as a program policy issue, but rather as an issue steeped in fraud, abuse and waste."

D. "[N]umerous people from within the industry have conceded publicly that AWP makes little sense as a basis for reimbursement."

E. "While AWP may be in excess of the acquisition cost of a drug (plus a reasonable markup), it does enable pharmacists to be reimbursed, albeit indirectly, for the necessary pharmaceutical services they do in fact provide. Since Medicare does not acknowledge the existence of these services, and thus does not provide for separate or additional reimbursement for them, the current use of AWP is the only means of paying pharmacists for what they actually do for Medicare beneficiaries."

Abbott Medicare Working Group document ABT 53263-53265. (Lavine Decl. Exh. 97)

121. One Ross Products division employee, Mr. Michael Tootell expressed his concern to Abbott in-house legal counsel about the legal exposure and potential negative consequence of AWP spreads. Tootell Dep. 199:17-22; 200:1-20; 202:1-11 (Lavine Decl. Exh. 112)

122. Abbott testified that prior to 2003 it did not understand that False Claims Act's reach included liability for reckless or inadvertent conduct in its price reporting. Fishman 30(b)(6), 3/20/08 at 643:10-22; 644:1-10. (Lavine Decl. Exh. 91)

123. Abbott never sought guidance from HCFA or HHS-OIG about Abbott's pricing activities or verify whether its pricing activities violated any law, including the federal False Claims Act. Abbott never asked Medicare or Medicaid officials whether it was permissible to

provide customers with spread or AWP information. Fishman Rule 30b6, 3/12/06 at 224:4-22; 225:1-6; 234:14-20; 240:10-22; Fishman 30(b)(6), 3/20/08 at 644:11-14. (Lavine Decl. Exh. 90, 91)

124. To Abbott's knowledge, Abbott's in-house counsel did not give any presentations to Abbott HPD concerning pricing or AWP, and Abbott cannot explain why in-house counsel did not give such presentations. Abbott's in-house counsel also did not give presentations concerning the provisions of spread and spread marketing. Fishman Rule 30b6, 3/12/08 at 95:12:15; 286:14-21; 287:2-6. (Lavine Decl. Exh. 90)

125. Abbott does not know whether prior to 2001 it took any steps to make sure that its reported HPD list prices approximated the prices paid by providers in its HPD Alt Site marketplace. Fishman 30(b)(6), 3/20/08 at 647:18-22; 648-649; 650:1-15. (Lavine Decl. Exh. 91)

126. Abbott claims that its HPD employees deferred to in-house counsel for ensuring HPD's compliance with Medicare and Medicaid and state and federal law and regulations. Abbott HPD employees never sought guidance from in-house counsel about Medicare and Medicaid compliance and legal and regulatory issues. Fishman Rule 30b6, 3/12/08 at 94:10-22; 95:1-5; 104:8-12; 143:5-22; 144-145; 146:1-4; 225:13-16; 226-227:228:1-2; Tobiason 1/22/08 Dep. 692:9-22; 693-699; 768:1-22; 769-771; 772:1-4; Baker 2/28/08 Dep. 360:10-22; 361-362: 363:1-13; 440:4-20; 443:2-22; 444:1-5; 515:11-22; 516:1-22; 517:1-5); Brincks Dep. 69:13-25; 70:1-22; Robertson 9/13/07 Dep. 130:11-25; 131:1-16; 137:11-25; 138:1-6; Robertson 10/9/07 Dep. 344:9-25; 345:1-16; Lynn E. Leone 1/17/08 Dep. 132:17-22; 133-136; 137:1-8; 245:5-22; 246:1-18; Karla Kreklow 2/7/08 Dep. 101:7-22; 102-115: 116:1-15; Sellers 11/1/07 30(b)(1) Dep. 173:1-22; 174-175; 176:1-22. (Lavine Decl. Exh. 90, 100, 104, 113, 114, 115, 116)

127. If Abbott contends that if employees had any questions about a statute or regulatory requirement, they should not have attempted to refer to them on their own, but should have consulted with the Legal Department. To Abbott's knowledge, no employee within HPD ever raised a concern to the Abbott Legal Department concerning HPD's pricing conduct and the compliance of its pricing conduct with Medicare and Medicaid. Abbott does not know if anyone made such inquiries to its litigation department. Fishman Rule 30b6, 3/12/08 at 317:11-18. (N-23) Fishman Rule 30b6, 3/12/08 at 104:8-12; 286:6-21. (Lavine Decl. Exh. 90)

128. The only review Abbott undertook to evaluate whether its pricing practices complied with Medicare and Medicaid fraud and abuse laws was undertaken by its legal department. Abbott has claimed that the evaluation is privileged and instructed its counsel instructed counsel not to answer questions concerning the evaluation. Fishman 30(b)(6), 3/12/08 at 335:5-22; 336-343; 344:1-22. (Lavine Decl. Exh. 90)

129. Abbott also refused, on the grounds of privilege[3], to provide testimonial evidence from its corporate representative concerning:

a. whether Abbott evaluated the legality of the spreads between its actual selling prices to customers and its AWPs;

b. advice regarding AWP, spread or spread marketing provided by Abbott in-house counsel to Abbott employees (even though non-legal employees were not permitted to review or interpret federal and state statutes and regulations); and,

[3]The United States specifically sought a Rule 30(b)(6) designee from Abbott to testify on efforts undertaken by Abbott to comply with federal and state law. Abbott designated David Fishman, an in-house Abbott lawyer, who refused upon instruction of counsel to answer many questions on the grounds of attorney-client privilege or on the grounds that the question called for a legal conclusion.

c. advice regarding price reporting, Medicare and Medicaid fraud and abuse (including concerning the federal Anti-kickback statute and the federal False Claims Act) provided by Abbott in-house counsel to Abbott employees.

Fishman Rule 30b6, 3/12/08 at 31:20-22; 32:5-22; 33-1-19; 35:7-22; 36-39; 40:1-18; 42: 20-22; 43-46; 47:1-8; 110:8-22; 111:1-7; 287:7-16; 295:2-22; 296; 297:1-21. 332:10-22; 333:1-22 (Lavine Decl. Exh. 90).

130. By at least April of 2007, Abbott's in-house counsel understood the relationship between AWP and reimbursement for Medicare. Abbott in-house counsels Mark Barmak and Anni Goldberg were involved in the litigation involving TAP Pharmaceuticals, Inc. ("TAP") and United States Department of Health and Human Services (HHS), in which TAP sought injunctive relief to preclude HHS from disallowing Medicare reimbursement for TAP's product Lupron at the Lupron's AWP. Abbott's in-house counsel also served as lawyers for TAP from 1989 until at least 1999. TAP was one client group for the Abbott legal department. TAP Lupron Complaint, Civ-Case No. 3-97-96919, U.S. Dist. Court for the District of South Carolina, at pp. 3-6, 11, 15, and related filings. Abbott response to U.S. Second RFAs 13; Trial Testimony of Mark Haberberger at 110-134; U.S. v. MacKenzie, et al, D. Mass. Criminal Case. No. CR-01-10350-DWP (Lavine Decl. Exh. 85, 86, 95, 127)

131. In 2001, TAP ultimately plead guilty to federal criminal charges ("TAP Criminal Case") in the District of Massachusetts, settled a civil action, and entered into a Corporate Integrity Agreement with HHS-OIG as a result of its conduct, in part, in creating and marketing high spreads. TAP paid a criminal fine of $290,000,000 and civil settlement payment of $559,482,560 incident to settling two related AWP lawsuits filed in the District of Massachusetts ("TAP Civil Actions"). In 2001, Abbott had to sign a letter agreement consenting to the criminal

plea and settlement. See Abbott Letter Agreement in TAP Case. (Lavine Decl. Exh. ___)

ABBOTT'S HOME INFUSION OPERATIONS

132. For its own pharmacies, Abbott would bill and collect any AWP spreads on its own products from third party payors such as Medicare and Medicaid. Abbott's only out-of-pocket expense was the cost of the product, and services carrying costs associated with storing and dispensing the product. Kreklow 121:4-22; Sellers 3/31/08 at 483:13-22; 484-485; 486:1-5 (Lavine Decl. Exh. 89, 116)

133. In addition to maintaining its own pharmacies, Abbott's Home Infusion business model was predominantly to contract with hospitals to help get them into the home infusion business. Sellers 30b6, 3/31/08 at 459:20-22; 460:1-11. (Lavine Decl. Exh. 89)

134. Abbott entered into "revenue share" arrangements with customers, including hospitals. Under these arrangements, Abbott offered a broad variety of services and options including:

a) the consignment of Abbott products and delivery to the revenue share partner's facilities without any upfront charge;

b) reimbursement services where Abbott employees would directly bill and collect from payors, including Medicaid and Medicare, on behalf of the revenue share partner;

c) pharmacy services and training;

d) the development of procedures that helped facilitate JCAHO accreditation;

e) engineering assistance for pharmacy build-out and warehouse and facilities start up;

f) case management on behalf of the revenue share partner for its patients; and,

g) access to the Abbott HPD "CHIPS" computer system.

Sellers 30b6, 3/31/08 at 460:19-22; 461; 462:1-22; 466:7-22; 467:1-5; Abbott response to U.S. Second RFAs 11 & 19. (Lavine Decl. Exh. 89 & 139)

135. In exchange for providing its consigned goods and broad services at no separate fair market value charge, Abbott would receive a percentage of the revenue share partners' collected billings from third party payors, including Medicare and Medicaid. Sellers 30b6, 3/31/08 at 466:1-6; 467:2-7. (Lavine Decl. Exh. 89)

136. If the revenue share partner was paid by Medicare or Medicaid for a product and that product enjoyed a spread between its AWP and market price, Abbott shared in a percentage of the spread that it collected from Medicare or Medicaid. Sellers 30b6, 3/31/08 at 460:19-22. (Lavine Decl. Exh. 89)

137. Pursuant to some of the revenue share contracts, if the revenue share partner elected to use a competitors' product for a particular therapy, instead of a product that Abbott consigned, the revenue share partner would still need to pay Abbott its agreed-upon revenue share for that therapy even though the revenue share partner paid for the competitor's product. (Home Infusion Documents) (Lavine Decl. Exh. 118)

138. Abbott never communicated to its clients or separately charged them any fair market value of the products it consigned or the services it provided. Sellers 30b6, 3/31/08 at 463:1-22; 464-466; 467:1-22. (Lavine Decl. Exh. 89)

139. The overall therapy category, and not the individual specific services provided to the patient, defined the revenue share percentage that Abbott collected. Sellers 30b6, 3/31/08 at 4689-22; 469:1-7; Home Infusion Documents (Lavine Decl. Exh. 89)

140. If Medicare or Medicaid did not pay for a particular patient's reimbursement, then

under Abbott's Home Infusion model, Abbott would provide the cost of the products used for the patients and for the cost of Abbott's services, and would recover nothing. Sellers 30b6, 3/31/08 at 469:9 -22. (Lavine Decl. Exh. 89)

141. Abbott advertised in its promotional materials for its Home Infusion unit that the arrangement was a "risk share"; if the revenue share partner did not collect, it did not have to pay Abbott for its products and services provided. (Home Infusion Documents) (Lavine Decl. Exhs. 118)

142. From its inception in 1983 through to its closure, Abbott Home Infusion's overall general format for its revenue share arrangements did not change, though the array of services provided may have varied from client to client. Sellers 30b6, 3/31/08 at 470:1-13. (Lavine Decl. Exh. 89)

143. Abbott's Home Infusion reimbursement department operated as follows:

a) the prescription was filled by the Abbott pharmacy or the revenue share partner;

b) an Abbott Home Infusion reimbursement team member would develop a claim and contact the payor, including Medicare and/or Medicaid;

c) there was a general time frame when the payor would be expected to reimburse. If the payor did not reimburse within that time period, Abbott would follow up;

d) if and when the payor paid, Abbott would get data from its pharmacies or revenue share partners' lockbox and document payment;

e) thereafter, if there were co-pays to collect, Abbott's reimbursement personnel would bill for co-pays because upon payment it would know

what the allowable amount was. At times, Abbott would also send out collection letters;

f) If Abbott or the revenue share partner did not accept a decision by a payor not to pay, or to disallow a portion of payment, upon agreement with the revenue share partner, Abbott would take an appeal through the payor's appeals process;

g) Abbott's Home Infusion business employed reimbursement technicians, also engaged in collections. In circumstances where a claim was denied by a third party payor, including Medicare and Medicaid, Home Infusion attempted to collect the entire amount which had been billed to the third party payor. In many cases, the amount "charged" by Home Infusion was based on a multiple of the AWP for the product**.**

Sellers 30b6, 3/31/08 at 473:2-22; 474-475; 476:1-12.; Collection Letter, Lavine Decl. Exhs. 93 and 94. (Lavine Decl. Exh. 89, 92, 93)

144. If the revenue partner used non-Abbott products for its patients, not only would the partner have to pay for that non-Abbott product, but by contract, that non-Abbott product cost to the revenue partner could not be was not deducted from the percentage share of the gross revenues that it was contractually required to pay Abbott. (Home Infusion Documents)(Lavine Decl. Exh. 118)

145. Under Abbott's Home Infusion business there was enough "profit" over and above ingredient cost for Abbott products that would permit both Abbott and its revenue partners to receive some form of return on investment. This margin resulted from the existence of high spreads and the low cost of Abbott consigned product. (Brincks Dep. 135:15-25; 136:1-5; 137-

147; 148:1-3)(Lavine Decl. Exh. 104)

146. Mr. Brincks testified that getting, for example, only 15 percent of a revenue partners' collections would enable Abbott to cover both the cost of the product and some incremental services if any were rendered. He further acknowledged that Abbott had to be aware that there were very significant spreads between the actual cost of the products and the reimbursement that was generated on those products. (Brincks Dep. 44:19-25: 45:1-4; 53:9-25; 54:1-3; 62: 21-25; 63:1-24; 144:24-25; 145: 1-23; 164:1-25; 216:14-25; 262:18-25: 263:1)(Lavine Decl. Exh. 104)

147. The following chart sets forth the range of spreads between the Average Price and the AWP for the 44NDCs at issue in this case. It is derived from the information contained in the spreads set forth in the Ormond Decl. As the summary show, the spreads for the Subject Drugs ranged 113% to 1685%:

NDC	Lowest Spread 1991 to 2000	Highest Spread 1991 to 2000	2001 Spread (Post List/WAC Reduction)
00074-1966-07	340%	783%	102%
00074-3977-03	479%	805%	91%
00074-4332-01	527%	1542%	269%
00074-4887-10	267%	1105%	100%
00074-4887-20	297%	731%	240%
00074-4887-50	164%	443%	102%
00074-4888-10	223%	811%	121%
00074-4888-20	282%	638%	109%
00074-6138-02	744%	1591%	n/a
00074-6138-03	754%	1351%	36%
00074-6138-22	1337%	1420%	64%
00074-6139-02	740%	1652%	n/a

00074-6139-03	757%	1301%	58%
00074-6139-22	1282%	1491%	55%
00074-6509-01	204%	708%	64%
00074-6533-01	493%	1675%	287%
00074-6534-01	113%	329%	111%
00074-6535-01	113%	351%	42%
00074-7100-13	268%	891%	44%
00074-7100-23	313%	885%	27%
00074-7101-02	299%	801%	73%
00074-7101-13	284%	859%	75%
00074-7101-23	283%	818%	43%
00074-7120-07	424%	993%	57%
00074-7138-09	872%	1535%	43%
00074-7139-09	868%	1546%	44%
00074-7902-09	650%	1310%	101%
00074-7922-02	540%	1174%	52%
00074-7922-03	701%	1148%	40%
00074-7922-09	540%	1175%	38%
00074-7923-36	291%	1071%	73%
00074-7923-37	581%	1349%	71%
00074-7924-09	702%	1450%	28%
00074-7926-09	685%	1074%	57%
00074-7941-09	701%	1274%	46%
00074-7972-05	112%	264%	49%
00074-7973-05	101%	329%	61%
00074-7983-02	478%	1204%	48%
00074-7983-03	998%	1240%	36%
00074-7983-09	446%	1391%	33%
00074-7984-36	276%	1082%	71%
00074-7984-37	510%	1094%	70%
00074-7985-09	689%	1378%	32%
00074-7990-09	424%	1122%	72%

Respectfully submitted,

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I hereby certify that I have this day caused an electronic copy of the above **STATEMENT OF UNDISPUTED FACT IN SUPPORT OF UNITED STATES' MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN OPPOSITION TO ABBOTT LABORATORIES INC.'S MOTION FOR SUMMARY JUDGMENT** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Mark Lavine

Dated: July 24, 2009 Mark Lavine